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John Ernest Hart

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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN E. HART

Appeal 2008-4225
Application 09/856,944
Technology Center 1600

Oral Hearing Held: November 20, 2008

Before DEMETRA MILLS, LORA GREEN and JEFFREY N. FREDMAN,
Administrative Patent Judges.

ON BEHALF OF THE APPELLANT:

DAVID SALIWANCHIK, ESQ.
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The above-entitled matter came on for hearing on Thursday, November 20, 2008, commencing at 10:12 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Suzie Dundas, Notary Public.

PROCEEDINGS

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JUDGE MILLS: Calendar No. 59, Mr. Saliwanchik.

JUDGE GREEN: Your application has been published now?

JUDGE FREDMAN: It's available on the web.

MR. SALIWANCHIK: I think this one was filed a pretty long time ago, so it probably has been published. But I'm not aware of it. I haven't thought about it.

JUDGE FREDMAN: I don't think it's been fully published. In light of the appeal, it may not have been published at all.

JUDGE MILLS: We'll err on the side of caution, I think.

MR. SALIWANCHIK: I don't think anyone's wanting to get in.

JUDGE MILLS: Okay. You have 20 minutes.

MR. SALIWANCHIK: Thank you. Well hopefully, actually I may be very brief. My name is Dave Saliwanchik, and I'm representing the Appellants, and really the main reason, if not the exclusive reason that I'm here, is just to answer questions that you might have or addressing the concerns that you have. I'm more than happy to just go ahead and do that, if there's anything that you're thinking about, or I can give maybe a little synopsis of the case, and if that brings any questions to mind, then that's fine as well.

JUDGE GREEN: I actually have questions.

MR. SALIWANCHIK: Sure.

JUDGE GREEN: Okay. Now the specification in this case is pretty sparse. I know it's a PCT. I can't tell, is this protein, I think it's micrin, this hormone, is it present all the time or is it only present in the post-when you collect them --

1 MR. SALIWANCHIK: Yes. My sense is that it is present
2 post-estrus, and that they had not found it at other times of the cycle. I think
3 it's present post-estrus, but most readily present if they induce it with a
4 clomiphene.

5 JUDGE GREEN: Okay. Now there are arguments that you don't
6 have to be ovulating to be able to produce the micrin. If you're in
7 ovulatory -- I think that's in some of the declarations.

8 MR. SALIWANCHIK: Right. I think the key is that it is obtainable
9 post-estrus, and it can be induced with a clomiphene. But it is by no means a
10 product of ovulation, that's correct. Which I think is one of the important
11 things that differentiates that from the protein in the cited reference.

12 JUDGE GREEN: Well, you look at diZerega, and in Example 1,
13 which is at Column 8 of diZerega, we have ovarian venous blood collected
14 from six women, two days after the onset of the last menstrual period. One
15 to three maintained regular menstrual cycles, while patients four to six were
16 non-ovulatory. It looks like they go through the vaccination, correct?

17 MR. SALIWANCHIK: Right. I think that's correct. So --

18 JUDGE GREEN: Then they say at the end that the one protein is
19 secreted by the pre-ovulatory ovary. But what would have happened in the
20 women who in anovulatory? What would have been present in their
21 collections?

22 MR. SALIWANCHIK: In the reference?

23 JUDGE GREEN: Yes.

24 MR. SALIWANCHIK: I don't know.

25

1 JUDGE FREDMAN: You declaration of Dr. John Hart in 2006 at
2 page seven, paragraph seven, says that "Micrin is detectable in ovulatory
3 individuals." So that makes it detectable in their blood. So you would think
4 that the micrin would be present in those women, that they would be
5 carrying it in their blood. But that just wasn't there.

6 MR. SALIWANCHIK: I think it's very hard to say whether it was
7 there or not. They certainly weren't looking for it. They didn't find it, and --

8 JUDGE GREEN: But our issue is anticipation. If they had gone
9 through and collected all the -- done all these steps and collected this
10 endogenous material, which didn't have the activity that they were looking
11 for, but that doesn't mean there could be some other kind of activity. Is it an
12 inherent, just speaking of your claim, and that's what --

13 MR. SALIWANCHIK: Right. So you're saying even forget the
14 protein that they found, the FRP.

15 JUDGE GREEN: Forget the protein, the FRP.

16 MR. SALIWANCHIK: Yes, I understand, and I think, you know, to
17 me the best answer to that is that we don't know whether it's there or not,
18 and --

19 JUDGE GREEN: Would that be a simple test to do?

20 JUDGE FREDMAN: Maybe with the burden issue, because they
21 collected the same blood. -- says it ought to be there. But then it seems like
22 why is that not a situation where it's in the data. He's made the best case he
23 can make, which it looks like he did, and the Examiner therefore has made
24 their case. It's up to you to decide about all these things, which may be --.

1 MR. SALIWANCHIK: Well, I think to me the question would be do
2 we really expect it to be there, and the claim specifically states that you're
3 collecting the blood from a post-estrus mammal. So that is an element of the
4 claim, and certainly our teachings throughout the specification emphasize
5 that, although it can be induced by the clomiphene. But I don't, you know,
6 to me, I don't know that there's any strong reason to suspect that it would be
7 there, in what the cited reference --

8 JUDGE GREEN: But your paragraph seven of the declaration
9 specifically says that micrin is present in ovulatory individuals. So this is a
10 case where your declarations would be -- for 102, if it is your material,
11 whether it would be recognized as the properties or not, it still anticipates
12 because it --

13 JUDGE FREDMAN: It has to be detectable.

14 MR. SALIWANCHIK: Well, it may depend specifically on how you
15 go about collecting it as well, and whether what the cited -- the procedure
16 that the cited reference went through would have in fact, you know,
17 collected that in amounts that would have been worthwhile. I mean I think
18 at some point there has to be --

19 JUDGE GREEN: But this is present in this particular level of
20 purification.

21 MR. SALIWANCHIK: I think --

22 JUDGE GREEN: All it requires is collecting the venus blood and
23 fractionating to get to this particular subfraction. That's the same subfraction
24 that the Examiner is looking at.

1 MR. SALIWANCHIK: But surely there should be some requirement
2 that what's collected for it to be inherent, that there has be some level there
3 that would be worthwhile or detectable. That's what we don't know is there.

4 JUDGE GREEN: No. I mean like in the SmithKline Apotex case,
5 which was the crystal --. The claim was to the compound itself, and even
6 though only a small amount was there, it was found to anticipate --

7 MR. SALIWANCHIK: At least it was found to be there. We don't
8 even really know whether it would be here, whether what --

9 JUDGE GREEN: No, but what we have -- what we have is we have a
10 declaration that says micrin is found in ovulatory individuals. What we have
11 is venous blood being collected from these ovulatory individuals. What we
12 have is we're collecting and we're fractionating the same way that you're
13 fractionating from plasma. To me, the burden then shifts for you to say well,
14 why wouldn't it be there?

15 MR. SALIWANCHIK: Okay. Let me just see exactly what he said in
16 what is it, paragraph seven--

17 JUDGE FREDMAN: Paragraph seven of the declaration.

18 JUDGE GREEN: Paragraph seven of the March 9th, 2006
19 declaration.

20 JUDGE FREDMAN: It says too that micrin is detectable in the blood
21 and is established in pre-ovulating individuals, but appears not detectable in
22 ovulatory individuals. Micrin is detectable in ovulatory individuals. That's
23 why I think it's not detectable in peripheral blood.

24 MR. SALIWANCHIK: Right, and you know, I'm not sure that what
25 he said there is that if you follow the procedure that the reference followed,

1 then you detect micrin. To me, he might be saying you can. You can find it,
2 and maybe he knows how to do it. But I don't think he's necessarily saying
3 that by following what diZerega did, you will have it there.

4 JUDGE GREEN: Yes, but they can't do the experiment, so we don't
5 know if it's there or not. Given the evidence that micrin is found in
6 ovulatory individuals and collected from plasma blood, in the same fashion
7 that you're claiming. It would appear to us that it's more likely than not that
8 it's there, and therefore the burden shifts. I understand that this is not the
9 rejection that the Examiner makes.

10 MR. SALIWANCHIK: No, I realize it, and it's not as if I had not
11 thought about this, although I didn't think about it in precisely the way that
12 you're proposing it, because I really did focus on the post-estrus. You're
13 specifically focusing on that statement that he made, and I think that's
14 obviously the key thing.

15 I'm just hesitant to read, you know, too much into what he said,
16 because he's saying it is there. It can be there, you can find it. But I'm not
17 sure if that's the same as saying if you do what diZerega did, you will have --

18 JUDGE GREEN: No, I understand that.

19 MR. SALIWANCHIK: But I'm -- sorry.

20 JUDGE GREEN: I'm following the shifting of the burden. Do we
21 have enough to shift the burden? If it can be there, then if it can be also -- it
22 could have also been in the batches that diZerega had obtained from these
23 ovulatory individuals.

1 JUDGE FREDMAN: You can clearly find it in other declarations,
2 and shift the burden back, by demonstrating that it isn't there and necessarily
3 in the prior art work. For that evidence to come into position, it's clearly got
4 to have a claim. The question is is this a sufficient base? Are we at, you
5 know, is there enough that we're going to shift the burden?

6 MR. SALIWANCHIK: Right, and to me, for there to be an inherency
7 rejection, you know, it does have to be there as a certainty. The fact that it
8 might be in there, and then even just stepping back further, I guess, and
9 saying okay, what is the purpose of anticipation or an inherency rejection,
10 you don't want to be moved from the public domain, what has already been
11 placed in the public domain.

12 And certainly this reference does not place into the public domain the
13 composition that we're claiming.

14 JUDGE GREEN: But it claims that. It fits there in partly the same
15 fraction and it's the same composition. That's my problem, is that you are
16 taking out of the public domain a composition that was made in the prior art,
17 even though it has property and it has something that was private, that was
18 not necessarily recognized. This goes back to the SmithKline case.

19 JUDGE FREDMAN: I think you could probably have this issue that
20 the micrin had not existed and you got the claim, and then relate it any time
21 afterwards. You'd probably --, because presumably you're getting a fraction,
22 assuming it's there and it's detectable.

23 MR. SALIWANCHIK: I think that you're right. It wasn't there in his
24 fraction. I don't think, my position obviously would be that there's not
25 enough there to say that it is for sure. But obviously that's the question, and

1 as far as I know, no one has followed the exact procedure of diZerega and
2 tried to figure out if the micrin was in there.

3 JUDGE GREEN: So we do have inherency. We do appear to have --.

4 MR. SALIWANCHIK: If you feel that there is, you know, sufficient
5 grounds to say that, with certainty that is in there.

6 JUDGE GREEN: Well, I do want to say that it's by a preponderance
7 of the evidence, right?

8 MR. SALIWANCHIK: Well, that's where I go back to the inherency.
9 For the inherency rejection to be proper, it did have to be there.

10 JUDGE GREEN: But with the best type situation, that it appears to
11 be the same. From what we can tell, it's more likely than not it is the same.
12 It's a burden-shifting thing. But then the burden shifts to you to show us
13 why we're wrong, because we can't go out and perform this ourselves. I
14 don't think that we have to have 100 percent of certainty to be able to do the
15 burden-shifting procedure, such as set forth in Best. Because we had 100
16 percent certainty there would be no reason to shift the burden; correct?

17 MR. SALIWANCHIK: Right.

18 JUDGE GREEN: So all we had to do is establish enough evidence to
19 say the burden shifts now to you, who has all of the information, who has the
20 procedures, who has the laboratory, to come back and tell us why we're
21 wrong. I mean I would love to be able to go out and perform the experiment
22 and see --

23 MR. SALIWANCHIK: Well, the unfortunate thing for us, you know,
24 is they're not going to want to do it. You know, they've been at this for so
25 long and it's been a really frustrating experience. Maybe we should have

1 anticipated that this would be an issue, instead of dealing with the issues that
2 we were dealing with.

3 But I'm not -- all I'm saying is the reality is it's going to be hard to go
4 back and say okay, well now it's --

5 JUDGE GREEN: I understand that. I do. You know, I feel for the
6 inventors. But still, we have to do the best we can under the law that's set
7 forth --

8 MR. SALIWANCHIK: So procedurally, if that was the direction that
9 you decided to go, it goes back to the Examiner with a suggestion to change
10 the rejection or --

11 JUDGE GREEN: More likely than not, we would enter a new ground
12 of rejection.

13 MR. SALIWANCHIK: Okay.

14 JUDGE GREEN: If we enter a new ground rejection, and you come
15 back on a request for rehearing and present your evidence. If you decide
16 you want to present your evidence, then you'd have to back and --.

17 MR. SALIWANCHIK: Right, okay.

18 JUDGE GREEN: Okay, because if you come back, the request for
19 rehearing has to be on the same record.

20 MR. SALIWANCHIK: Okay.

21 JUDGE FREDMAN: Of course, if they further testify that they
22 obtained it in a purified form, that testimony would be more acceptable. If
23 it's a certain fraction, they'd already go down --. I mean to say there are
24 ways they can get a patent on this in spite of diZerega, even if we accepted
25 that everything was true. We're saying --.

1 JUDGE GREEN: But unfortunately, only -- is your course of action.

2 MR. SALIWANCHIK: Right, and presumably the method of use
3 would --

4 JUDGE FREDMAN: But there would be also a difference in the
5 results.

6 JUDGE GREEN: Right, right.

7 MR. SALIWANCHIK: Because of the coaching that diZerega
8 purifier --

9 (Simultaneous discussion.)

10 JUDGE GREEN: Unless an alternative -- or something.

11 MR. SALIWANCHIK: Yes, and we have a -- we currently have an
12 invention pending, that there might be an avenue for pursuing some of this
13 rather quickly as well.

14 JUDGE GREEN: But -- this is at all -- prosecution. It's a lot less
15 expensive than --.

16 JUDGE FREDMAN: They used a purifier at the end of the
17 sequence -- very valuable. That would be --.

18 MR. SALIWANCHIK: I appreciate your input and having thought
19 about it carefully.

20 JUDGE MILLS: Okay. Anything else you'd like to add?

21 MR. SALIWANCHIK: No thank you.

22 JUDGE MILLS: Okay, very good. Thank you very much.

23 (Whereupon, at 10:26 a.m., the oral hearing was adjourned.)

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